OPIOID AGONIST TREATMENT IN THE 21st CENTURY

Although methadone has been the cornerstone of opioid addiction treatment for nearly 30 years, its use remains controversial and the scientific basis for its efficacy is not widely appreciated. Methadone maintenance is the most effective approach currently available for persons addicted to heroin and other opioids. The large body of data available on its safety and efficacy has resulted in a consensus within the medical community that it is a valuable treatment modality for many heroin addicts. But, unfortunately, many in the general public are not aware of the medical consensus and, contrary to the scientific evidence, express strong negative feelings about methadone despite the large number of studies that have demonstrated its efficacy.

When properly used in conjunction with appropriate psychosocial services, methadone and its recently approved, longer-acting opioid agonist counterpart, LAAM, helps patients stop using heroin and other opioid drugs. Opioid agonist treatment programs (OTPs) have also been effective in reducing other illicit drug use, helping those addicted to opioids become more productive citizens, enhancing public health and community safety by reducing the transmission of infectious diseases (e.g., HIV, hepatitis) and decreasing criminal activity.

Nonetheless, the methadone treatment system that was built in the 1970s has consistently and frequently been attacked by the media and by legislators at all levels. Some of the criticisms of poorly run, often under-funded clinics have been justified. Others have been inspired by insistence on total abstinence from any agonist medications, or consternation about the multiple social, criminal, and psychological problems frequently manifested by persons who use illicit substances. In recent years, funding for methadone treatment has eroded at the same time that heroin use has been increasing, particularly among young people who tend to snort the more potent forms now available in combination with crack and cocaine use. The AIDS epidemic among injection drug users has further strained the resources available for methadone treatment.

General Strategies to Modernize Treatment of Opioid Addiction

Faced with these challenges, the Substance Abuse and Mental Health Services Administration (SAMHSA), through the Center for Substance Abuse Treatment (CSAT), is undertaking three parallel strategies to ready the addiction treatment system for the new millennium:

- 1) reform the federal regulations governing the use of methadone and LAAM in OTPs;
- 2) develop options so that well-stabilized methadone/LAAM patients who no longer need intensive psychosocial services can be treated by private physicians in regular office settings; and
- 3) establish alternative treatment delivery models that incorporate new medications with different characteristics that are more immediately acceptable to mainstream medicine as well as to potential patients (e.g., buprenorphine/naloxone).

The purpose of this paper is to address the first, and most fundamental, of these initiatives. The other two strategies are being tackled through separate processes, i.e., a CSAT-established consensus panel of experts from the field that is developing clinical guidelines for office-based opioid treatment—medical maintenance, and the work of a subcommittee on buprenorphine that is part of CSAT's National Advisory Council.

Over the past year, the Department of Health and Human Services (DHHS) has conceptualized ways to modernize and reform the methadone treatment system so that it remains a necessary but solid foundation for the other two proposed initiatives and, at the same time, provides even more benefits to the patients served. This paper reviews the background for these proposed reforms, outlines the recommended mechanisms for addressing critical problems, and delineates the improvements that are anticipated to result—in due time—from regulatory reforms.

Why Regulatory Reform of the Methadone Treatment System is Critical

The regulatory system that controls many aspects of opioid addiction treatment has come under increasing scrutiny in recent years. Improvements are needed in the oversight mechanisms, as well as in the specific rules that govern methadone/LAAM treatment. Unlike most therapeutic medications, methadone has been subject to detailed treatment standards initially issued in 1972 by the Food and Drug Administration (FDA)—before methadone's medical safety and effectiveness for treating narcotic addiction were proven, and while illicit distribution was widely feared. Although slightly modified in subsequent years, these federal methadone regulations still govern how and where, as well as by and to whom, methadone is administered and dispensed. No other medication or aspect of medical care is so tightly regulated by the federal government.

During the intervening years:

- The characteristics and associated health and mental health problems of patients receiving methadone therapy have changed dramatically.

- Knowledge about the neurobiological components of addiction has increased substantially.

- Opioid addiction has been declared a treatable medical disorder (NIH Consensus Panel, November 1997).

- Studies have found that methadone is not intrinsically attractive as a drug of abuse, and that "*it is not often diverted for recreational or casual use, but rather to individuals with opiate dependence who lack access to ....treatment programs*." (Institute of Medicine, December 1994)

- A new era of managed health care challenges all substance abuse treatment programs to implement policies and procedures that emphasize cost containment, accountability,

quality assurance, patient/consumer participation, and continuous assessment and improvement of patient outcomes.

Sources for Regulatory Reform Recommendations

The impetus for reform of the methadone regulatory system has come from several sources, including discussions among providers and other experts in the addiction field about proposed changes in the federal regulations, recommendations from blue-ribbon committees, and other field studies of methadone treatment programs.

Reactions to Notices of Proposed Rule-Making (NPRM)

Respondents to proposed revisions of the methadone regulations over the past decade have offered many suggestions regarding ways to promulgate standards and monitor compliance.

Report by the General Accounting Office (GAO) on Methadone Maintenance, 1990

In response to a request from the House Select Committee on Narcotics Abuse and Control, the GAO reviewed the treatment provided to patients in a sample of 24 methadone maintenance programs, the effectiveness of services in reducing drug use among patients, and the impact of the government's oversight role for these programs. The GAO found wide disparity across OTPs in the services provided, and minimal federal oversight.

Institute of Medicine Report on Federal Regulation of Methadone Treatment, 1995

In 1992, the U.S. Public Health Service requested that a specially convened committee at the Institute of Medicine (IOM) evaluate the effects of federal regulations on methadone treatment and explore options for modifying the regulations to encourage optimal clinical practice. The committee's findings are cogently summarized in the statement that "*The current regulations produce unintended results: addicts who cannot obtain a treatment program tailored to their individual circumstances; physicians who are unable to exercise professional judgment in treating individual patients; programs that are isolated from mainstream medical care (thus depriving patients of important ancillary services); and significant economic costs in assuring compliance with regulatory requirements.....*"

The Interagency Narcotic Treatment Policy Review Board (INTPRB)

An interagency Federal committee, composed of representatives from FDA, SAMHSA, DHHS, the National Institute on Drug Abuse (NIDA), the Drug Enforcement Administration (DEA), Department of Veterans Affairs (VA) and the Office of National Drug Control Policy (ONDCP), has existed since 1970 to consider and resolve opioid-related issues across federal agencies in relation to law enforcement responsibilities, regulatory practices, treatment approaches, and policies. This group was asked to consider the IOM Report and determine whether and which of

its recommendations should be accepted. The Board readily agreed on several revisions that would both satisfy federal requirements and improve the quality of treatment.

The Office of Medical Applications of Research at the National Institutes of Health (NIH) organized a non-federal, non-advocate, 12-member panel of professionals from six health-related

the topic of medical treatment of opiate addiction. In November 1997 the panel developed conclusions from the evidence presented and the scientific literature.

The deficiencies noted and recommendations made by these various committees and studies can by categorized into the following four general areas.

- *The system for monitoring compliance with federal treatment regulations is inefficient.*

  costly, and redundant. The IOM Report recommended a review of the enforcement policies, procedures, and practices pertaining to methadone treatment by all governmental

  for comprehensive inspections conducted by one agency.

  The INTPRB agreed that a regulatory model for compliance and enforcement—that

  acceptable substitute for the existing FDA inspection process. More recently, the NIH Consensus Panel again suggested that "
  improving the quality of methadone maintenance treatment (MMT) programs should be instituted these changes in the current regulatory system...[would be expected] to reduce unnecessary costs both to MMT programs and to enforcement
  ."

-

  The GAO Report commented on the very limited federal oversight of methadone programs during the period 1982-1989 when the FDA's field resources were limited. In

  once to close a poorly functioning methadone program. The IOM Report again took note of this problem by noting that an effective enforcement effort must close seriously

Inappropriate and Inflexible Federal Methadone Regulations

- *The federal methadone regulations unnecessarily restrict the practice of medicine.*

  The IOM Report was particularly harsh in concluding that the federal regulations pose an undue administrative burden, infringe on clinical authority, and either don't affect—or have an adverse impact on—patient outcomes and the quality of services. The NIH Consensus Panel argued that federal regulations that "*prescribe methadone treatment procedures in minute detail*"should be eliminated altogether. In support of this recommendation, the Panel observed that current laws and rules impose "*an extra level of regulation on methadone compared to other Schedule II narcotics,"* that"*these regulations seem to have little if any effect on quality of ...care,*" and "*However well intended the FDA's treatment regulations were when written in 1972, they are no longer helpful*."

- *The regulations governing methadone/LAAM are rigid and discourage clinical judgment.*

  The NIH Consensus Panel also affirmed the "*critical importance, in improving methadone maintenance treatment (MMT).....[of recognizing that,] as in every other area of medicine, treatment must be tailored to the needs of the individual patient. Current federal regulations make this difficult if not impossible*."

  The IOM committee had similarly remarked that greater clinical discretion in determining appropriate medical treatment should be encouraged. Moreover, the Narcotic Addict Treatment Act of 1974 required the dissemination of appropriate standards, not necessarily rules. Such standards might be issued in the form of clinical practice guidelines modeled on the Treatment Improvement Protocol (TIP) series published by CSAT. In fact, a shift to clinical guidelines would both allow practitioners greater flexibility and also permit more frequent modifications to keep guidelines current with changes in the field. Whereas promulgation of revised federal regulations is a time-consuming and difficult process, changes in clinical guidelines can be accomplished by expert peer review and circulation of proposed revisions to the field.

  However, the IOM Report recommended that clinical practice guidelines supplement and complement —not replace—a core of existing federal regulations that is still needed to *proscribe* certain substandard or unethical activities. Guidelines alone are not enough to assure that patients are cared for in safe and thoughtful manner. Among the enforceable, mandatory requirements advocated by the IOM Report are:

  1) comprehensive rehabilitative services, not just counseling, that are available either on-site or by referral to meet the assessed needs of individual patients;

  2) ongoing clinical assessments of patients throughout treatment, rather than any

services offered;

3) clear procedures for involuntary administrative withdrawal of medication—that give attention to due process;

4) no arbitrary limitations on take-homes doses for the sole purpose of controlling

5) no attempts to promote withdrawal from methadone without counseling patients about the probability of relapse; and

behavior.

•

An ongoing criticism of the federal methadone regulations is that they focus exclusively on

perform all of the required procedures and still not know whether the procedures are effective for ameliorating or resolving patients' problems. The GAO was particularly

programs develop and use result-oriented performance standards.

While the IOM Report agreed that formal quality assurance systems offer a promising

responsibility from regulators to clinicians, practical mechanisms for measuring treatment effectiveness are not yet well-developed in the addictions field. More work needs to be

as performance indicators, that could be used for assessing the quality of methadone treatment programs. An alternative, at this point, is to focus on continuous quality improvement mechanisms that do not have fixed standards of treatment, but involve programs in measuring outcomes, attempting to reduce the variation around the level of average performance and, at the same time, improving average performance.

Variability in the Quality and Comprehensiveness of Treatment for Opioid Addiction

The GAO Report and other field studies of methadone treatment programs (e.g., Ball and Ross, 1991; D'Aunno and Vaughn, 1992) document a wide disparity in treatment practices, particularly in such areas as drug screening/testing requirements, staffing credentials, dosage levels, restrictions on take-home doses, types and intensity of rehabilitative services offered, and discharge policies. Research studies have demonstrated that counseling and other professional health care and social services are important components of opioid addiction

treatment—particularly during its initiation—that significantly improve the social, psychiatric, and health status of patients with multiple problems.

Unfortunately, NIDA's Drug Abuse Treatment Outcome Study (DATOS) reported a marked decrease between 1991-1993, compared with 1979-1981, in the number and variety of available clinical and support services in OTPs. The IOM Report similarly noticed that the "*present system of care offered by methadone maintenance programs has deteriorated badly over the past ten to fifteen years while the number, chronicity, and complexity of the problems presented by patients have increased (e.g., AIDS, TB, cocaine, crime).*" Moreover, "*it is in the public interest to address the 'addiction related' problems of unemployment, crime, and infectious diseases*."

Inadequate Treatment Capacity and Accessibility

Nationwide, methadone programs treat approximately 125,000—or 15 percent—of an estimated 810,000 heroin addicts. Although not all of these active users of heroin or other opioids might choose to enter or be eligible for maintenance on methadone or LAAM, there is still a sizeable gap between capacity and the number of users. The demand for methadone treatment varies considerably across regions of the U.S., with waiting lists for admission in some places such as New York City. Eight states prohibit methadone treatment and its availability is seriously limited in most rural areas. Other policies and practices such as unaffordable out-of-pocket fees in some facilities, restrictive zoning, inconvenient hours of operation, or fears about stigmatization further limit access to care for some potential patients.

The limited treatment capacity is, in large part, a result of inadequate public funding and the lack of reimbursement coverage by private health plans. The IOM Report suggests that fundamental structural improvements in the methadone treatment system that bring it into the mainstream of medical care could pave the way for more reimbursements by Medicaid and other insurers. The NIH Consensus Panel expects that; "*If extra levels of regulation were eliminated, many more physicians and pharmacies could prescribe and dispense methadone, making treatment available in many more locations than is now the case*." Also, "*if some additional physicians ...treat a few patients each, aggregate access to methadone treatment would be expanded.*" Finally, any reductions in program costs incurred by preparing for and undergoing multiple inspections and by targeting needed services to the initial stages of treatment could be used for expanding treatment capacity.

An Action Plan to Reform the Methadone/LAAM Treatment System

Over the past several years, CSAT has worked with the FDA to help revise the regulatory approach that governs the federal monitoring system for methadone/LAAM treatment programs and determines medical and other clinical practices within these facilities. The goals of the proposed changes are to make federal oversight more effective, to permit greater flexibility in medical and clinical practice, and to reduce variability in the quality of services offered.

A Notice of Proposed Rule-Making (NPRM) has been drafted for publication in the Federal Register in the Spring of 1999, with a 120-day period for public comment and a public hearing before a Final Rule is adopted. This document proposes (a) the transfer of administrative responsibility from FDA to SAMHSA for overseeing and monitoring OTP compliance with federally-mandated methadone/LAAM regulations and (b) issuing revised treatment standards. It also specifies procedures for switching from a monitoring system of FDA inspections to an accreditation model in which SAMHSA-approved entities, including States, will survey OTPs on a systematic and periodic basis. The NPRM also specifies a core of federal requirements for opioid treatment that must be incorporated into accreditation standards.

A CSAT-directed Impact Study has been initiated to assess the effects of accreditation on a representative group of OTPs, using accreditation standards developed by the Commission on Accreditation of Rehabilitation Facilities (CARF) and the Joint Commission on Accreditation of Health Care Organizations (JCAHO) that incorporate clinical guidelines for methadone treatment generated by the field. The CSAT accreditation guidelines were drafted by two expert panels convened in December 1996 and January 1998. The panels used a modified consensus approach to prepare a document that was circulated to the field for review and comment before incorporating suggested revisions into the final guidelines. These guidelines, together with the accreditation standards, provide a quality improvement template for OTPs. They have been widely disseminated to the field at the American Methadone Treatment Association national conferences, CSAT workshops and through the CSAT web site (www.treatment.org).

Technical Assistance (TA) will be provided by CSAT and will be specifically targeted toward aiding OTPs to improve treatment services. The needs of State governments related to methadone treatment will also be addressed. These efforts will include workshops targeted on improving the quality of treatment and its accessibility for OTPs, increasing communication among State and Federal officials, and providing expert resources from the field of substance abuse treatment to areas of need throughout the country. The TA will be designed to assist OTPs to interpret and implement State and Federal regulations and standards and related accreditation standards; to make needed changes in organizational structure and personnel; to modify treatment processes and monitor outcomes; and to prepare for and maintain accreditation.

In sum, major reforms of the regulatory system that has governed OTPs and ensured compliance with rules for nearly three decades, are expected to resolve the most frequently expressed criticisms offered by experts in the field. Reform will result in a modernized treatment system with a more effective and widely acceptable national oversight mechanism, accreditation. It is also envisioned that state-of-the-art clinical practices will attract physicians in mainstream medicine; comprehensive services will be available to meet the individually-determined needs of patients; services will be of sufficient quality to be reimbursable by Medicaid and other third-party insurers; and access to treatment will be expanded. These reforms are expected to attract many previously unserved or under-served persons with opioid addiction who, by entering and responding to treatment, will improve not only their own health and functioning, but the public health and safety of the communities in which they reside.